

Docket No.: 64593-092



**PATENT**

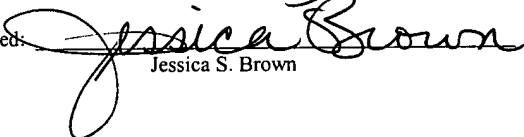
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of : Customer Number: 33401  
SHEHADA, Ramez E.N. et al. : Confirmation Number: 1472  
Serial No.: 10/775,666 : Group Art Unit: 3763  
Filed: February 9, 2004 : Examiner: Not Known  
For: **SURGICAL DRAIN WITH SENSORS FOR MONITORING INTERNAL TISSUE  
CONDITION**

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited  
with the United States Postal Service as First Class Mail to: Mail Stop  
Petition, Commissioner for Patents, P. O. Box 1450, Alexandria, Virginia  
22313-1450 on December 23, 2004.

Signed:

  
Jessica S. Brown

**PETITION TO MAKE SPECIAL UNDER 37 C.F.R. § 1.102(d)**

Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Applicants hereby petition to make the application identified above special in accordance  
with 37 C.F.R. § 1.102(d) and M.P.E.P. § 708.02(VIII).

Compliance with the requirements of M.P.E.P. § 708.02 (VIII) is established by the  
following:

**Fee**

Please charge Deposit Account 501946 the amount of \$130.00 as set forth in 37 CFR  
§ 1.17(h) to cover the fee for the present Petition to Make Special. Attached is a fee transmittal  
form for this purpose.

**Single Invention**

If the Office determines that all the claims presented are not obviously directed to a single invention, Applicants will make an election without traverse and invite the Examiner to contact the Applicants' undersigned representative for a telephonic election.

**Pre-Examination Search**

Applicants submit that a pre-examination search has been made. The field of search included International Class 600, Subclasses 475 and 478, and International Class 604, Subclasses 541, 31, 93.1, 20, 21, 96.1, 100.1, and 104-106.

**Copy of References**

Copies of the references deemed most closely related to the subject matter encompassed by the claims are included with the accompanying Information Disclosure Statement.

**Detailed Discussion of the References**

The following is a detailed discussion of the references, including with particularity how the claimed subject matter is patentable over the references.<sup>1</sup>

**Overview of Invention**

The invention is directed to a surgical drain that includes a sensing system for sensing a property of tissue in proximity to the drain. Each claim specifically requires one or more of the following:

- a sensor attached to a surgical drain having holes along substantially its entire length
- making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain
- monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system
- dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces
- transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue
- detecting spectral energy of tissue proximate to a drain and displaying a color

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<sup>1</sup> Applicants do not represent that each reference is prior art or that the most pertinent portion of each has been summarized. The references are numerous and, in many cases, complex. The Examiner is asked to independently review them.

- representative of the tissue based on the spectral energy
- detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy

As demonstrated by the following discussion, none of the references of record, individually or in combination, anticipates the claimed subject matter or renders it obvious.

**U.S. Patent 6,556,851 to Ott et al.**

Ott et al. disclose a detection probe for spectroscopy and/or spectrometry in tissue (4) with the aid of optical fibers (1,2). Abstract. At least one fiber (2) transmits light into the tissue (4) and other fibers (2) receive backscattered light. Id. Deflection devices (mirrors 6, fibers 7, prisms 9,10,11) are provided for the light. Abstract.

However, Ott et al. do not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

**U.S. Patent 6,547,761 to Liu**

Liu discloses a drainage catheter that includes a dilating member 100 with one or more arms 110. Abstract. Flexing or extending the arms 110 respectively serves to anchor the medical device 98 in the body of the patient. Title; 4/50-59. Abstract.

However, Liu does not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time

using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

**U.S. Patent 6,491,682 to Paderni**

Paderni discloses an apparatus for extracting fluids from a body that utilizes a pressure application system. Title; 7/13-16.

However, Paderni does not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

**U.S. Patent 6,437,855 to Wilson et al.**

Wilson et al. disclose signal processing methods for processing Laser Doppler Velocimeter (LDV) signals. Abstract. A true Doppler frequency is extracted from the phase noise frequencies by maintaining a highest frequency value. Abstract. The highest frequency value is replaced with any measured frequency values that are higher than the current highest frequency value. Abstract. This is continued for a predetermined lifetime period, after which the highest frequency value is stored and then reinitialized. Abstract. The highest detected frequency values over a window of lifetimes are then averaged to provide a moving or rolling average value which is indicative of the velocity of a medium. Abstract.

However, Wilson et al. do not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

**U.S. Patent 6,411,838 to Nordstrom et al.**

Nordstrom et al. is directed to examining a sample using a substantially monostatic, substantially confocal optical system comprising transmitting optics that focus an illuminating light upon the sample and receiving optics that collect light emitted from the sample following illumination thereof. Abstract. In certain embodiments, the receiving optics may be arranged circumferentially around the light path traversed by the illuminating light. Abstract. In certain embodiments, video apparatus may be included to produce images or to align the system in proximity to the target tissue. Abstract. The systems and methods of the present invention may be directed towards the examination of a body tissue to provide a medical diagnosis. Abstract.

However, Nordstrom et al. do not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting

spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

#### **U.S. Patent 6,334,064 to Fiddian-Green**

Fiddian-Green discloses a tonometric device for use in hollow viscous tonometry and remote sensing of patient fluid parameters is disclosed in combination with a secondary apparatus, such as a urinary catheter, a nasogastric sump apparatus, or a feeding tube, for example. Abstract. The device is capable of monitoring certain critical fluid properties of interest, such as oxygen gases and carbon dioxide gases in the wall tissue itself of the patient's organ, rather than monitoring such properties in a lumen of the organ. Abstract. A walled sampling chamber, which is preferably an inflated balloon member, is provided on an elongated tube, with provisions for positioning the sampling chamber in direct contact with a wall portion of the patient's internal organ. Abstract.

However, Fiddian-Green does not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

#### **U.S. Patent 6,134,460 to Chance**

Chance discloses a tissue oximeter sensor which utilizes a light source(s) that transmits wavelengths toward the localized tissue of interest and a detector exposed to receive photons of the specific wavelength that have originated from each light source, and scattered from the localized tissue and passed back to the detectors. 3/49-61. The system detects the oxygenation state of hemoglobin within the muscle. 8/48-50.

However, Chance does not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

**U.S. Patent 5,965,873 to Simpson et al.**

Simpson et al. disclose a spectrometer that comprises: a semiconductor having a silicon substrate, the substrate having integrally formed thereon a plurality of layers forming photo diodes, each of the photo diodes having an independent spectral response to an input spectra within a spectral range of the semiconductor and each of the photo diodes formed only from at least one of the plurality of layers of the semiconductor above the substrate; and, a signal processing circuit for modifying signals from the photo diodes with respective weights, the weighted signals being representative of a specific spectral response. Abstract. The photo diodes have different junction depths and different polycrystalline silicon and oxide coverings. Abstract. The signal processing circuit applies the respective weights and sums the weighted signals. In a corresponding method, a spectrometer is manufactured by manipulating only the standard masks, materials and fabrication steps of standard semiconductor processing, and integrating the spectrometer with a signal processing circuit. Abstract.

However, Simpson et al. do not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a

transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

**U.S. Patent 5,916,171 to Mayevsky**

Mayevsky discloses a single signal-single probe multiparameter analyzer apparatus for monitoring various parameters of the identical volume element of body tissue, which includes an input signal generator, a single signal guide which transmits input signal in, and transmits output signal out, constituting a single signal-single probe, a signal splitter which splits output signal into two or more parts, filters which separate various components of output signal, detectors which measure the different components of the output signal, a computer and an analog to digital converter; and algorithms to evaluate the data. Abstract.

However, Mayevsky does not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

**U.S. Patent 5,746,207 to McLaughlin et al.**

McLaughlin et al. disclose a biosignal electrode device comprising a flexible electrically insulating substrate 11 having deposited thereon an electrically conductive layer forming an electrode sensor 14 and a lead 15 for the sensor. Abstract. The portion of the substrate bearing the sensor is formed in relief such that the sensor stands above the surrounding substrate. Abstract.



However, McLaughlin et al. do not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

#### **U.S. Patent 5,685,313 to Mayevsky**

Mayevsky discloses a single signal-single probe multiparameter analyzer apparatus for monitoring various parameters of the identical volume element of body tissue, which includes an input signal generator, a single signal guide which transmits input signal in, and transmits output signal out, constituting a single signal-single probe, a signal splitter which splits output signal into two or more parts, filters which separate various components of output signal, detectors which measure the different components of the output signal, a computer and an analog to digital convertor; and algorithms to evaluate the data. Abstract.

However, Mayevsky does not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

**U.S. Patent 5,645,062 to Anderson et al.**

Anderson et al. disclose a biomedical electrode device that comprises an electrically insulating substrate carrying an electrode. Abstract. The electrode is coated with a moisture-activated electrically conductive bioadhesive layer having an adhesion of between 50 and 500 g/cm.<sup>sup.2</sup> and a water content of less than 25% w/w. Abstract.

However, Anderson et al. do not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

**U.S. Patent 5,512,045 to Gurchumelidze**

Gurchumelidze discloses an apparatus (10) and method for surgical decompression and irrigation/lavage of a patient comprising a tube (12) having a distal end (14) which is inserted into the intestine and a proximal end (16) which is located outside the patient. Abstract. The tube (12) has a wall which surrounds a plurality of longitudinally extending lumens. Abstract. A suction lumen (22) is connected to a suction means located exteriorly in relation to the patient. Abstract. There are one or more pores capable of delivering irrigation fluid and for syphoning the contents of the patient's intestine. Abstract. An irrigation lumen (24) is connected to irrigation means (32) located exteriorly in relation to the patient. Abstract. There are one or more openings extending from the suction lumen (22) to the irrigation lumen (24) for ducting irrigation fluid or gastrointestinal content and for avoiding plugging of the pores by particulate matter or by a stomach lining when the stomach is aspirated. Abstract.

However, Gurchumelidze does not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed

by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

**U.S. Patent 5,349,961 to Stoddart et al.**

Stoddart et al. disclose a methodology and apparatus for the clinical evaluation of biological matter, in particular human anatomy, examined in situ and in vivo, by selective spectral light transmissivity. Abstract. An optical probe introduces selected light spectra into the examination subject at a first position and resulting light intensity at a second position located some distance from the infusion point is measured; also, light reception preferably occurs at at least one other location, and the effective distances between these locations and the infusion point are determined. Abstract. The light energy received at the distant points is quantified and conditioned by use of the effective distances from the infusion point and/or from one another, and also by contrasting the data from the two differently-located reception points, such that the resulting data quantitatively characterizes intrinsic internal tissue characteristics in an absolute sense, devoid of particular individual characteristics and variations such as skin pigmentation, boundary composition or state, etc. Abstract. The methodology is especially characterized by the selection and use of particularly-located first and second light-reception positions whose locations with respect to the point at which the light spectra are introduced define particular zones of interrogation and analysis, and whose location with respect to one another may be comparatively examined (e.g., differenced) to selectively define a particular internal volume whose structure or conditional state is to be examined, quantified, and/or analyzed, all of which is accomplished on a non-intrusive in vivo basis. Abstract.

However, Stoddart et al. do not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by

dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

**U.S. Patent 5,337,748 to McAdams et al.**

McAdams et al. disclose a biosignal electrode 10 which comprises a flexible substrate 1 having an obverse side and a reverse side, the obverse side having printed thereon an electrically conductive layer 2 comprising an ink having electrically conductive particles or mixture of particles therein, the layer in plan comprising a first or sensor end 11, a second or connecting end 12 and an interconnecting portion 13, and the sensor end in plan resembling a hollow figure.

Abstract.

However, McAdams et al. do not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

**U.S. Patent 5,108,364 to Takezawa et al.**

Takezawa et al. disclose a main tube having a hollow portion that forms a passageway for discharging liquid such as body fluids. 3/29-31. The tip portion of the lead (4) is located near the

tip portion of the body of the catheter (1) and temperature sensor (10) is mounted to the tip portion thereof so as to measure temperature at a specific area of the body cavity. 4/3-7.

Takezawa et al. disclose that it is also possible to provide a plurality of lead (4) and simultaneously measure temperatures at a plurality of regions. 4/21-26.

However, Takezawa et al. do not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

#### **U.S. Patent 5,106,387 to Kittrell et al.**

Kittrell et al. disclose diagnosis of the type of tissue in an artery, including distinguishing artery wall from atheromatous plaque, in which a catheter with one or more optical fibers is enclosed at a distal end by an optical shield transparent to light radiation and wherein the proximal end of the catheter and optical fibers are coupled to a source of optical radiation. Abstract. The catheter is inserted into an artery until the optical shield is brought into contact with a suspected arterial lesion or other tissue to be diagnosed. Abstract. Spectral energy may be shown in a display. 19/52-55. Kittrell et al. also appear to disclose optical fibers embedded in a transparent optical shield (12) that forms part of the catheter. 7/50-63.

However, Kittrell et al, do not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a

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#### **U.S. Patent 4,721,115 to Owens**

Owens discloses a multi-lumen catheter having a balloon-like expander located at the distal end thereof, the interior of the balloon communicating with one of the plural lumens whereby a fluid introduced at the proximal end of the catheter can be made to inflate the balloon. Abstract. A series of surface electrodes are axially spaced over a zone located near the distal end of the catheter body. Abstract. Electrical conductors connected to each of the surface electrodes pass through another lumen to an electrical connector at the proximal end of the catheter. Abstract. A pair of stiffener members, one being co-extensive with the zone of the catheter bearing the axially spaced surface electrodes and the other being spaced a short predetermined distance proximally of the first stiffener member are in another lumen. Abstract. The gap between the two stiffener members allows the catheter to bend without kinking the lumens so that, when used, the most proximal ring electrode will be disposed near the apex of the right ventricle with the portion distal of the bend extending upward through the outflow tract of the right ventricle. Abstract. Further lumens and ports communicating therewith may be added to permit the catheter to be used to take thermal dilution measurements of cardiac outputs. Abstract.

However, Owens does not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of

tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

**U.S. Patent 4,654,029 to D'Antonio**

D'Antonio discloses an electronic drainage system that includes transducers in a drain that monitor characteristics of fluid flowing through the drain (temperature) and evaluation of fluid which has been expelled from the drain (volume, weight). Title; 6/53-59; 7/41-45.

However, D'Antonio does not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

**U.S. Patent 4,416,285 to Shaw et al.**

Shaw et al. disclose a catheter apparatus having transmitting and receiving optical fibers for photometric analysis of a fluid eliminates the need for individually calibrating each catheter within a population of catheters by making substantially uniform the center-to-center spacing between the outlet aperture of each and every transmitting fiber and the inlet aperture of each and every receiving fiber of an individual catheter for all catheters within a population of catheters; and by making the size and shape of all the outlet apertures of all transmitting fibers generally uniform and the size and shape of the inlet apertures of all receiving fibers generally uniform in each catheter and from catheter to catheter and that the orientation of all transmitting fibers relative to all receiving fibers be similar. Abstract.

However, Shaw et al. do not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by

dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

**U.S. Patent 4,317,452 to Russo et al.**

Russo et al. disclose a flexible body fluid drain tube has substantially flat cross section with a pair of parallel longitudinal internal ribs along one substantially flat wall which are spaced apart a distance greater than their respective distances from the adjacent edges of the flat wall, a central internal longitudinal rib along the opposite substantially flat wall, and a pattern of drain holes along both flat walls in line with the parallel ribs. Abstract. The ribs prevent the tube from collapsing even when the tube is subject to a very high vacuum and/or strong lateral compression forces due to body movements of the patient and the healing process at the drainage site. Abstract. The central rib can wipe back and forth across the opposite wall to keep the tube passageway and drain holes clear when the flat tube walls are moved laterally relative to one another by body movements of the patient and the healing process. Abstract.

However, Russo et al. do not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of



tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

#### **U.S. Patent 3,866,599 to Johnson**

Johnson discloses a catheter of the fiberoptic type for insertion into the cardiovascular system. Abstract. The catheter comprises a flexible element with light-conducting fibers therein extending from one end of the element to the other. Abstract. A recess is provided adjacent one end of the catheter to prevent the optical fibers from contacting a vessel wall when the catheter is inserted therein. Abstract.

However, Johnson does not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

#### **U.S. Patent Application Publication 2002/0082587A1 to Noda**

Noda discloses a Foley catheter that has redundant temperature sensors to enable use of the Foley catheter with a patient heating system, such as one relying on a vascular heat exchange catheter. Abstract. The temperature sensors electronically couple with a control unit, which obtains a primary temperature reading from one of the temperature sensors and obtains a secondary temperature reading from the other temperature. Abstract. The control unit compares the primary and secondary temperature reading to determine a sensor temperature difference. Abstract. When the sensor temperature difference exceeds a predetermined value, then the control unit activates an alarm, shuts down the patient heating system, or both. Abstract.

However, Noda does not disclose a sensor attached to a surgical drain having holes along substantially its entire length; making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

### **O2C Probes Manufactured by LEA Medizintechnik**

Applicants have uncovered that this German company manufactured and sold an optical sensor that measured in-vivo tissue and organs to determine tissue oxygenation, perfusion and hemoglobin. This occurred prior to the filing date of this application. A variety of materials concerning this product are submitted with Applicants' Information Disclosure Statement.

Applicants also uncovered an abstract of an article that made reference to this product and stated, *inter alia*:

An implantable version of the probe, launched in December, can be inserted in an auxiliary drainage catheter in organ transplant patients to monitor the blood and oxygen supply to transplanted kidneys, livers, hearts and other organs. Detection of impaired flow or low oxygen delivery can allow the surgeon to re-intervene at an early stage . . . . “

Applicants also had an investigation performed during which the following was verbally reported by the company:

The way the probe is used is by inserting it into a drainage hose and cutting a hole at the end of the drain to enable the sensors to be in direct contact with the tissue to be examined. Sometimes it is preferable to stitch the probe laterally to the drain. If the position of the sensors is good, i.e. in direct contact with the tissue and secure enough that it won't move with the movement of the animal/patient. If the position is bad, then the researcher has to decide whether to stitch it or glue it. Sometimes, if the access site into the body is very small, there is almost no need to fix the probe additionally. It is then sufficient to close the access site well to keep the probe in place.

However, Applicants were unable to obtain any information that demonstrated that this alleged use of the product took place in the United States. Applicants have also been unable to obtain any information that suggests that the concept of inserting the probe into a drainage hose was set forth in a printed publication that was published prior to the January 2003 date of the publication quoted above.

In any event, this information does not appear to constitute a disclosure of making a comparison between the information sensed by dual sensors configured to sense a physiological property of tissue in proximity to outer surfaces of a drain; monitoring a physiological property of tissue in proximity to an implanted drain over time using a sensing system; dual drains, each with dual sensors on opposing surfaces that sense a physiological property of tissue proximate to the surfaces; transmitting spectral energy from a transmitting system to tissue in proximity to a drain and receiving spectral energy from a sensing system from that tissue; detecting spectral energy of tissue proximate to a drain and displaying a color representative of the tissue based on the spectral energy; or detecting spectral energy of tissue proximate to a drain and displaying a color value representative of the tissue based on the spectral energy.

### Conclusion

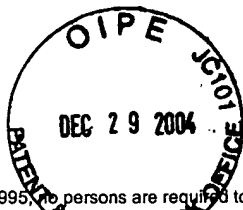
For the foregoing reasons, it is respectfully submitted that this Petition to Make Special should be granted.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 501946 and please credit any excess fees to such deposit account.

Respectfully submitted,  
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**Date: December 23, 2004**



PTO/SB/17p (11-04)

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**PETITION FEE**  
**Under 37 CFR 1.17(f), (g) & (h)**  
**TRANSMITTAL**

(Fees are subject to annual revision)

Send completed form to: Commissioner for Patents  
P.O. Box 1450, Alexandria, VA 22313-1450

Application Number	10/775,666
Filing Date	February 9, 2004
First Named Inventor	SHEHADA
Art Unit	3763
Examiner Name	
Attorney Docket Number	64693-092

**Enclosed is a petition filed under 37 CFR 1.102(d) that requires a processing fee (37 CFR 1.17(f), (g), or (h)). Payment of \$\_\_\_\_\_ is enclosed.**

This form should be included with the above-mentioned petition and faxed or mailed to the Office using the appropriate Mail Stop (e.g., Mail Stop Petition), if applicable. For transmittal of processing fees under 37 CFR 1.17(i), see form PTO/SB/17i.

**Payment of Fees** (small entity amounts are NOT available for the petition fees)☒ The Commissioner is hereby authorized to charge the following fees to Deposit Account No. 501946:☒ petition fee under 37 CFR 1.17(f), (g) or (h) ☒ any deficiency of fees and credit of any overpayments

Enclose a duplicative copy of this form for fee processing.

☐ Check in the amount of \$\_\_\_\_\_ is enclosed.☐ Payment by credit card (Form PTO-2038 or equivalent enclosed). Do not provide credit card information on this form.**Petition Fees under 37 CFR 1.17(f): Fee \$400 Fee Code 1462**

For petitions filed under:

- § 1.53(e) - to accord a filing date.
- § 1.57(a) - to accord a filing date.
- § 1.182 - for decision on a question not specifically provided for.
- § 1.183 - to suspend the rules.
- § 1.378(e) - for reconsideration of decision on petition refusing to accept delayed payment of maintenance fee in an expired patent.
- § 1.741(b) - to accord a filing date to an application under § 1.740 for extension of a patent term.

**Petition Fees under 37 CFR 1.17(g): Fee \$200 Fee Code 1463**

For petitions filed under:

- § 1.12 - for access to an assignment record.
- § 1.14 - for access to an application.
- § 1.47 - for filing by other than all the inventors or a person not the inventor.
- § 1.59 - for expungement of information.
- § 1.103(a) - to suspend action in an application.
- § 1.136(b) - for review of a request for extension of time when the provisions of section 1.136(a) are not available.
- § 1.295 - for review of refusal to publish a statutory invention registration.
- § 1.296 - to withdraw a request for publication of a statutory invention registration filed on or after the date the notice of intent to publish issued.
- § 1.377 - for review of decision refusing to accept and record payment of a maintenance fee filed prior to expiration of a patent.
- § 1.550(c) - for patent owner requests for extension of time in *ex parte* reexamination proceedings.
- § 1.956 - for patent owner requests for extension of time in *inter partes* reexamination proceedings.
- § 5.12 - for expedited handling of a foreign filing license.
- § 5.15 - for changing the scope of a license.
- § 5.25 - for retroactive license.

**Petition Fees under 37 CFR 1.17(h): Fee \$130 Fee Code 1464**

For petitions filed under:

- § 1.19(g) - to request documents in a form other than that provided in this part.
- § 1.84 - for accepting color drawings or photographs.
- § 1.91 - for entry of a model or exhibit.
- § 1.102(d) - to make an application special.
- § 1.138(c) - to expressly abandon an application to avoid publication.
- § 1.313 - to withdraw an application from issue.
- § 1.314 - to defer issuance of a patent.

  
MARC E. BROWN

Typed or printed name

December 23, 2004

Date

28,590

Registration No., if applicable

This collection of information is required by 37 CFR 1.17. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 5 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.